DEVICE, SYSTEM AND METHOD FOR STORING AND EXCHANGING MEDICAL DATA

The present invention relates to a portable
5   electronic storage device, a system and a method for
storing and exchanging medical data.

Patients need confidentiality and privacy. This
need is so strong that there are even laws such as the
privacy law, and healthcare professionals are obliged to
10   swear their oath of office. These laws and obligations
ensure that patients (including users in general) have and
want to have a strong control in who may know what about
their own health status. On the other hand, patients want a
care provider to supply a good and fast diagnosis. The
15   pressure to produce a good and fast diagnosis is high
because the patient mostly wants to start as soon as
possible with the correct treatment.

For a good diagnosis, exactly the right amount of
information is required. In case of too much information,
20   available essential information may be missed. In case of
too little information, essential information might not be
present. The patient decides which information he or she
gives to the healthcare professional, but the patient is
not always sure whether the information given is sufficient
25   and describes exactly the right picture. The patient does
not always give all the information necessary for a good
diagnosis. This happens easily when the patient is either
ashamed of this information or when this information is old
and presumed not important.

30   If the patient gives information which involves
other healthcare professionals, the professional wants to
check the integrity and completeness of the given medical
information by consulting those other professionals, before
continuing the diagnosis or treatment. This also takes time

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and correspondence. The given response is not always as
expected and mistakes in this communication are very
difficult to check.

Because of the above-discussed social situation,
5   it has been proven very difficult to set up a central (e.g.
national) database that can track, protect and maintain all
medical data from all patients. Consequence to this is that
healthcare professionals collect and store the data of
patients, resulting the situation that information of each
10 patient is fragmented over multiple healthcare
professionals and the medical records may even be
distributed over multiple locations.

The wish for organized and accessible medical
data was the reason why software was developed to maintain
15 a medical database on a personal computer or laptop. The
advantage of this software is that medical data on one
disease of one person is complete. In practice, this
solution has resulted in lack of compatibility with the
different computer systems of the individual healthcare
20 professionals.

Internet sites exist where patients can enter
their medical data so that each healthcare professional,
with the right authorisation, can look at these data. The
problem here is that the patients have to enter the medical
25 data themselves, therefore the medical integrity of the
data cannot be guaranteed. Besides this, this system
requires not only a computer but also an Internet
connection from the healthcare professional. Additional to
this, the data is less safe, because anybody can
30 anonymously try to access the personal medical data, even
multiple times.

Additionally, many patients do not want their
files passed on by means of Internet or e-mail. Non-
authorised passage of their medical files is relatively too

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easy, and the disorder concerning security of Internet use
is contrary to the requirement of confidentiality of
medical information. Furthermore, patients and healthcare
professionals remain concerned about the security of data
5   on Internet. There are many examples of leaks of sensitive
data, because of insufficient security. A large database of
medical information attracts hackers, criminals or even
terrorists. If a medical database is used for sharing
information, important for diagnoses and treatments, the
10 contents of these data must be complete and accurate; until
now this can not be guaranteed.

In order to overcome the drawbacks of keeping
sensitive medical data on a remote Internet servers,
systems have been developed wherein medical dossiers are
15 kept in portable electronic devices. Examples of existing
systems and methods for using portable medical dossiers are
described in the patents US 5.899.998 by McGauly, US
5.499.293 by Behram et al., US 6.082.776 by Feinberg and US
2.003.088.440 by Dunn B. Rentz.

20   One of the drawbacks of the known systems is that
the electronic device carried by the patient only contains
the medical data of the patient. One of the implications is
that the medical data is only accessible by people and
institutions that have at their disposal the specific
25 physical interfaces and the specific software needed to
access these data. The portability is strongly reduced by
this restriction.

Another drawback is that the known systems
provide for the storage of data for medical use only.
30 However, it can be of vital importance to be fully aware of
a patient's general health condition during treatment.
Information such as weight, drug use, diabetes etc. might
be useful in the assessment of the general health condition
of the patient.

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A further drawback of the prior systems is that possible lifesaving functionality is missing. If, for instance, a patient is unable to give user and password information, the emergency healthcare professionals and

5   ambulance personnel may not be able to read the stored information that can be vital and crucial for emergency treatment of the patient.

It is therefore an object of the present invention to provide a system, device and method wherein at

10   least one of the drawbacks of the prior art is obviated.

According to a first aspect of the present invention a system is provided for storing and exchanging medical data, the system comprising:

- a plurality of portable electronic storage devices,

15   each storage device comprising an interface and one or more data carriers on which are stored medical data representative of the health of at least one individual and a computer program;

- a data processing device comprising:

20   - a second interface for connecting the data processing device to at least one of the portable electronic storage devices,

- a processor configured so as to load from the connected portable electronic storage device the computer

25   program and executing the same, the loaded computer program including instructions that cause the processor to process the medical data stored on the portable storage device, said processing including reading, adding and/or modifying medical data stored on the connected portable electronic

30   storage device;

- a display device for displaying said processed medical data.

The system reduces the chance of misdiagnosis since the medical data is more readily available to the

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healthcare professional. Therefore the results of
misdiagnosis caused by for example interaction of different
medications prescribed by different healthcare
professionals, use of medications which influence other
5   sicknesses than the one prescribed for, and medications
and/or allergies not known by emergency or ambulance
personnel can be avoided. Furthermore, the system enables a
quicker diagnosis to be made.

Another benefit for patients may be the feedback
10   of information, such as results of treatments, to
scientists and researchers. In this way current treatment
and development of new medication can be improved, and bad
or insufficient treatment and medications can be stopped.
Incidentally, medical data as described herein include (but
15   are not limited to) data representative of a person's
medical condition and health in general.

In a preferred embodiment the system comprises a
first portable electronic storage device being configured
so as to store thereon medical data in a first data format
20   and a second portable electronic storage device being
configured so as to store thereon medical data in a second
data format, different from the first format.

Preferably a first computer program is stored on
the first portable electronic storage device that is
25   capable of having processed medical data in the first
format, while on the second portable electronic storage
device a second computer program is stored capable of
having processed medical data in the second data format.

According to a further preferred embodiment the
30   system comprises a portable electronic storage device on
which is stored a first and a second computer program, the
first computer program being operable so as to exchange
medical data with a data processing device of a first type
en the second computer program being operable so as to

exchange medical data with a data processing device of a
different type.

According to a further preferred embodiment
access to the medical data on the electronic storage device
5   is protected by an access code, preferably a password. In
another preferred embodiment a first user or group of users
has data reading rights only. In an even further preferred
embodiment a second user or second group of users has
reading and adding rights only. In a still further
10 preferred embodiment a third user or third group of users
has reading, adding and modifying rights of medical data
stored or to be stored on the electronic storage device.
The rights might be given for all medical data stored on
the storage device. Preferably however the reading, adding
15 and/or modifying rights are for a predefined subset of
medical data only.

In a further preferred embodiment the computer
program is operable so as to permit the addition of a new
user or group of users only after receiving the correct
20 access code of said individual. This will provide the
individual, for instance the owner of the storage device,
always the control over the grant of reading, adding and/or
modifying rights to others.

In an even further preferred embodiment the
25 computer program is operable so as to permit access to a
predefined portion of the medical data only after receiving
the correct access code of said individual. This predefined
portion of the medical data can in this case only be
accessed by the individual or by a third party to which the
30 individual has provided an access code.

In an especially preferred embodiment the
processing device is a mobile phone and the electronic
storage device is an external storage medium that can be
connected to the mobile phone or, in another embodiment,

the processing device is a mobile phone and the electronic
storage device is an internal storage medium contained in
the mobile phone. Both embodiments have the advantage that
the medical data is stored in an electronic device that

5   nowadays a large part of the population keeps has close at
hand. Furthermore, use can be made of the processor and
display device available in the mobile phone to
respectively process and display the medical data.

In another embodiment, however, the data

10   processing device is a personal computer, for example a
personal computer, stand alone computer, server, laptop,
palmtop, handheld, or PDA.

In still another preferred embodiment the
electronic storage device is configured so as to be

15   implanted in a person. In the implanted device both the
software and the data are stored as well. Data exchange to
and from the implanted storage device is wireless, for
example using a radiofrequency transceiver.

In another preferred embodiment the electronic

20   storage device comprises a positioning system. Whenever
necessary the patient can be traced by the positioning
system, for example a GPS or Galileo module. When the
person is traced and found, immediate medical help can be
given if necessary, with the medical/health data stored in

25   the electronic storage device.

The interfaces of the data processing device and
the portable electronic storage device may be wireless
communication devices to provide a wireless connection
between the portable electronic storage device and the data

30   processing device or may be wired communication devices to
provide a wired connection between the portable electronic
storage device and the data processing device.

According to a preferred embodiment the computer

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program is operable so as to provide text on the display
device in one of a plurality of languages, said one
language being user selected from a pre-stored list of
languages.

5   According to another aspect of the invention a
portable electronic storage device is provided for storing
and exchanging medical data with a data processing device
having an interface, a processor and a display device,
wherein the portable electronic storage device comprises a

10   data carrier on which is stored medical data representative
of the health of at least one individual and a computer
program, wherein the computer program, when run on said
processor, causes said processor to process the medical
data stored on the data carrier, said processing including

15   reading, adding and/or modifying medical data stored on the
connected portable electronic storage device, and
displaying said processed data on the display device.

          Further advantages, features and details of the
present invention will be elucidated on the basis of the

20   following description of a preferred embodiment of the
invention. In the description reference is made to the
accompanying drawings, in which:

          Figure 1 is a schematic representation of a
preferred embodiment of the present invention,

25   Figure 2 is a flowchart showing the login process
to enter the storage device of figure 1;

          Figure 3 is a window showing the emergency
selection screen on the display of a data processing
device;

30   Figure 4 shows a main menu screen;

          Figure 5 shows an emergency review screen;

          Figure 6 shows a medication consumption
registration screen;

          Figure 7 shows a diet screen of a health dossier;

Figure 8 shows a protected medical detail screen of a medical dossier;

Figure 9 shows the example of a pre-stored function examination test screen;

Figure 10 shows the example of a pre-stored cardiology test screen, including pre-stored medical data;

Figure 11 shows an example of a medicine information screen; and

Figure 12 is a schematic view a further embodiment of a portable electronic storage device according to the present invention.

One of the goals of the present invention is that the healthcare professional, at the moment that the healthcare professional finds it necessary, has access to the complete health status of the patient, so that the healthcare professional can choose, select and pick all the information assumed needed for a diagnosis, treatment, advice or other action.

Figure 1 shows a first preferred embodiment of the system according to the present invention. The figure shows a portable electronic storage device 1 that can be connected (directly or wirelessly, as will be explained later) to an input/output unit (I/O) of a data processing device, for example a USB memory stick that can be inserted into the USB port of a computer. Besides the input/output unit a data processing device comprises typically a central processing unit (CPU), a memory (MEM), a data storage unit (STOR), a display (DIS), etc. To the processing devices might be connected peripherals, such as a printer 7. Examples of processing devices are personal computers (stand alone or part of a network), server computers, laptops, palmtops, PDA's and/or handheld portable phones.

The input/output unit (I/O) of a data processing device may be a wired unit using a cable, a piece of

hardware, or a wireless unit using for example an infrared
connection, a direct radiographic connection (Bluetooth,
WiFi or the like) or a connection by satellite. It is noted
that the input/output units of the data processing devices

5   do not have to be the same or of the same type. The
portable storage device comprises one or more data carriers
on which the medical data and/or health data and the
control program are stored.

A non-limitative list of examples of data

10 carriers includes USB Memory sticks, Memory cards, Chip
cards, Cards with magnetic strips, Interactive watches,
Digital video and / or photo camera's, Palmtop / handheld,
Notebook, laptops, Hard discs / mini-hard-discs, CD Rom /
CD Rom writable / CD Rom rewritable, DVD, Mini disc, or an

15 ID card with an uplink to a central database, where the
patient has given authorisation for storage of his / her
medical data.

Figure 1 shows a plurality of data processing
devices 2-6 of various persons and / or institutions that

20 use the present system. Processing device 2 is the computer
of a patient, processing device 3 is the computer of a
healthcare professional, for instance a general
practitioner, a dentist, a specialist, an infant welfare
centre or a therapist, processing device 4 is the computer

25 of a pharmacist, processing device 5 is the computer of an
insurance company and processing device 6 is the mobile
phone of emergency personnel. The download and upload
processes 8-12 indicate the data streams between the
portable storage device 1 and each of the processing

30 devices 2-6, while data stream 13 indicates data streams
from a processing device 2-6 to a peripheral device 7. The
storage device comprises a database 17 containing medical
and/or personal data of the user, encryption software 16
for encrypting and decrypting the data to be stored on the

storage device 1 and the general software 15 responsible
for handling the medical data (reading, writing and
modifying the medical data and processing the same).

The software may be written in any programming
5   language (e.g. C++, C#, Visual Basic, Java, XML, XMS and
many others). The data in the database 17 may be of any
type, including text, audio- and/or video data (sound
fragments, photographs, pictures, X ray plots, drawings,
schemes, presentations, (MRI) scans). Examples of
10 appropriate databases are SQL, MySQL, MS Access, Oracle, MS
Excel, Dbase, foxpro, Paradox, ODBC, Xbase, Lotus 1 2 3,
XML, XMS, text files and user defined databases and / or
files.

Once the electronic storage device 1 has been
15 connected to any of the data processing devices 2-6 the
user, i.e. the patient, the healthcare professional, the
pharmacist, the insurance company, or the emergency
personnel respectively, must gain access to the software
and data stored on the storage device 1. To accomplish this
20 the user has to login to the electronic storage device.

Figure 2 shows a flowchart of a preferred login
process to the electronic storage device. When the storage
device 1 is connected properly to the processing device
(i.e. any of the devices 2-6), the processing device loads
25 and executes the software or parts of the software 15
stored on the storage device 1. Then the processing device
looks whether a database 17 is present on the storage
device 1 (step 100). If this database is not found, a
dialog-box appears (step 101) on the display (DIS) of the
30 processing device 2-6 stating that the database 17 was not
found and prompting the user to specify the location of the
database.

If the processing device finds the proper
database, it performs a check (step 103) whether the serial

number in the database matches the one found on the storage
device 1. If the serial number does not match the one
found, a warning goes out and the program terminates (step
104).

5   If the serial number does match the number found
on the storage device 1, the processing device will then
enter the actual login procedure (step 106) by choosing
from one out of three operational modes, i.e. login in case
of emergency, create a new account or login as an existing
10   user.

If the login in case of emergency (step 107) mode
is chosen, the emergency care provider will have to select
the proper user (patient) by identifying both his/her name
and identity photograph. To this end, the processing device
15   shows on its display (DIS) a window including the name and
a photograph of the patient, as is shown in figure 3. If
the emergency care provider identifies the patient
positively as one of the users of the portable storage
device 1, the patient can be selected (step 108) which will
20   cause the processing device to continue to the main menu
(step 111). The main menu is schematically shown in figure
4 and contains a number of buttons 20-26. In the present
operational mod some of the buttons can be activated by the
user, in this case the emergency care provider, while other
25   buttons are blocked from being activated by the user. Since
the emergency care provider has only limited access rights
the data in the medical database 17, it is only a small
subset of the buttons that is selectable in the present
operational mode. In other words, only the emergency
30   section of the medical dossier can be activated in the
present mode.

One of the buttons that can be selected in the
emergency mode of operation is the "emergency review"
button 23. When emergency review button 23 is activated,

the processing device generates an emergency window. Only
information crucial for stabilizing the patient will be
made available in this window. A part of the contents of
the emergency overview comes from the personal database.

5   Another part will has been entered specifically separately.
This way the patient has maximum control over which data is
to be shown there and which data may not be shown. An
example of a emergency window is shown in figure 5. The
window shows the name, gender, age, blood group, list of

10   medicines used by the patient, a list of health complaints,
etc.

        Additionally, emergency care providers may need
to access the medication consumption registration to see if
and how good medication has been taken and what the

15   reaction of the patient was. To this end the emergency care
provider can first select the "medication consumption
registration" button 22. Activation of this button will
cause the processing device to access the database 17 and
search for information regarding the history of the

20   consumption of particular medicines. Figure 6 shows a
window 28 displaying consumption registration data of a
particular medicine. For instance, the window may show the
name of the medicine (codeine), the dose, the consumption
dates and times, and the side effects.

25   In some preferred embodiments other screens are
made available by the software 15 as well, for example
screens for providing access to a medical encyclopaedia
stored on the storage device 1 and/or screens for changing
the language of the windows.

30   If the create a new account (step 110)
operational mode is chosen, the new user is requested to
enter a username, enter a password and retype the password
to be sure the passwords match. If the username and the

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password are set, the main menu is displayed (step 112) and
the new user can start adding personal or medical data.

If an existing user intends to gain access to the
medical database, he or she will is requested to enter a

5   password (step 109). If the password is correct the program
continues to the main menu (step 112) and the user may
start to add all information wanted in the appropriate
records of the database.

Accessing the personal information field by

10   activating the "personal details" button 20 (figure 4) will
cause the processing device to create and display an input
window in which the user, in this case the owner of the
storage device 1, can add, remove or modify personal
information, such as name, address, age, number of identity

15   papers and card-data, insurances, phone numbers, addresses,
etc..

Accessing the personal health page by pressing
the 'personal health records' button 21 will cause the
processing device to provide access to the database records

20   associated with the personal health of the owner(s) of the
storage device 1, such as the dossiers diet, donations,
blood sugar levels, addictions and blood pressure
measurements, as will be explained hereafter.

Figure 7 shows the personal diet window 32

25   wherein the user can enter information about his weight
(start weight and target weight, weights measured in a
predefined time interval). Based on the entered information
the processing device generates a chart 33 wherein the
measured weights are depicted as function of time. In

30   another dossier (not shown), measured blood sugar levels
are entered and stored in the database 17. The processing
device is able to generate a number of graphs, each showing
the measured blood sugar levels as function of the time of
day. When two or more graphs showing the measured blood

sugar levels on different days are displayed
simultaneously, they may be compared easily to obtain a
better understanding of the course of the blood sugar level
in time.

5   Accessing the medical dossiers by pressing the
"medical history" button 24 will give access to a plurality
of medical dossiers associated with the owner or owners of
the portable storage device 1. Firstly of all the
processing device checks which medical records are present
10   in the database 17, generates a list of available medical
records and displays the list in a medical record selection
window on the display (DIS). After selecting a particular
medical record, a first window pertaining to the selected
medical record is shown on the display of the processing
15   device. Figure 8 shows an example if a first window of a
medical record provided (and owned) by the general
practitioner. The content of this medical record is
protected by username and password of the general
practitioner. In succession, the general practitioner can
20   take a few possible actions:

- Do nothing / give advise

- Give medication

- Perform some tests or let others perform tests

- Refer to medical specialists

25   In case the general practitioner does nothing or
gives advice, this can be stored in the current record. No
other field is required. In case the general practitioner
wants to give medication, a further screen (window)
appears, wherein the general practitioner can add the
30   medicine prescribed, the amount, how many times a day, how
many days etc. The general practitioner can also choose a
medication from a list of medications, the list being
imported from a pre-stored list of available medicines from

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database 17 on the portable storage device 1. In case the general practitioner wants to perform some test, a further screen (window) appears wherein the practitioner can choose from a list of tests, the list being imported to the

5   processing device from a pre-stored list of available (standard) tests from the database 17 on the portable storage device 1. The present screen is the same screen as a specialist doctor will see when a specialist wants to perform some tests. The general practitioner (or the

10   specialist) may for example choose from the following tests:

- Endoscopic test;

- Function examination;

- Laboratory;

15   - Microbiological;

- Nucleair examination; and

- X-ray.

Figure 9 shows an example of a window 34 that is generated by the processing device wherein the results of

20   one or more function examination tests can be filed. The processing device generates the window 34 based on a standard format pre-stored on the storage device 1. The format is pre-stored on the storage device 1 in order to provide general practitioners (or specialists) for each

25   function examination test with a data input (and/or output) window having a uniform layout. Window 34 includes a button 35, at the activation whereof a further window 36 is displayed. The further window 36 (figure 11) shows a number of charts 37, in the present case Electro Cardiograms and

30   Electro Encephalic grams.

The general practitioner may refer a patient to a hospital or a clinic to obtain more specialised research, treatment and care. In this case, information that is more

specific will be more useful. First the new owner of the
record (i.e. the specialist in the hospital) has to set his
or her password for the new record. Some data are already
available to the specialist while these data is inherited
5   from the general practitioner's record. For example, the
name, address, date of birth, telephone numbers are
inherited from the personal dossier of the user(s). Other
data or more specific details are still to be entered. Some
examples of standard format medical dossiers are emergency,
10   internal healthcare, plastic surgery, intensive care,
cardiology, etc. Incidentally, the medical dossiers are
designed as template and may therefore be easily adapted to
the hospital's or individual healthcare provider's needs.
When medical records are created, information about the
15   healthcare providers involved in the treatment of a certain
individual user and/or about the medications taken by the
individual user becomes available. These two groups can be
sorted out to give an overview. In this way another
specialist or the individual user can view a list of the
20   specialists involved or all medications given. Figure 11
gives an example of a window 40 to be shown on the display
(DIS) of the processing device. The window shows
information about the medicine "codeine" used by patient.
Pressing button 41 on window 40 can activate the earlier
25   described window 28 displaying consumption registration
data the present medicine (cf. figure 6). In this way
information about the actual consumption of the medicine
(consumption dates and times, the side effects, etc.) is
readily available.
30   Referring to the main menu shown in figure 4 a
user of the system may activate the "encyclopaedia" button
25. When opening the encyclopaedia, the following
information that has been pre-stored on the storage device

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1, may be made available to the owner of the storage device and/or to the other users of the storage device:

●   Dangerous substances

●   Addresses

5 ●   Medical terms

●   Internet links

Regarding a selected dangerous substance, an advice notice may be given on the most safe action(s) that has (have) to be taken. When a selection is made, people

10 can see whether the victim has to bring up the substance, drink milk, drink water or do nothing. Does the victim need to be brought to the hospital or not, etc. The second part of the encyclopaedia is the address book. Here addresses of medical/health involved institutions and medical/health

15 involved persons can be entered. The third part of the encyclopaedia is the medical terms book. The meaning of thousands medical expressions is explained. The last function of the encyclopaedia is a links field. By categorised groups the user can browse through medical and

20 health related organisations, institutions and websites.

Referring to the main menu shown in figure 4, a user of the system may activate the "change language" button 26. Activating this button will cause the processing device to translate the language of the pre-stored texts in

25 the windows of the system.

Figure 12 shows a further preferred embodiment of a portable electronic storage device according to the invention. In this embodiment the electronic storage device is integrated in a mobile phone 51, for example a GSM-

30 telephone. The mobile phone comprises a battery- (54) powered micro-controller (CON) 53 that is connected through a data bus 59 with a memory 52. On memory 52 is stored the software and data normally present for operating the mobile

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phone and the control software 15 and encryption software
16 and the medical database 17 according to the present
invention. In another embodiment (not shown) the software
15,16 and database 17 are stored on a separate memory
5   device, for example a memory stick, that can be coupled to
the mobile phone. Keyboard 56 may be used for controlling
the software 15 and entering data into the database 17,
while the standard display 55 can be used to display
processed data from the medical database 17. The mobile
10 phone further comprises a transceiver 60 connected to the
antenna 58 for communication with the mobile telephone
network. The mobile phone 51 also comprises a second
transceiver for short-distance communication, for according
to the Bluetooth™ protocol. Communication with a data
15 processing device 2-6 is established in a wireless manner
using the first transceiver 60, or, preferably, the second
transceiver 61.

Concerning security, integrity and control of the
database and the information contained in the database the
20 following remarks can be made. The access to the medical /
health data / information is secured with a username and a
password. The owner has to log in before the data /
information is accessible. Also the data inside the
database is encrypted. Medical records such as medical
25 dossiers, dental records and therapies are protected with a
username and password of the owner (which is the healthcare
professional). Only the proprietor of a particular record
can change the contents by adding, modifying or removing
data, or the entire record. In this way, the authenticity
30 of the entered data is guaranteed. For instance, if the
healthcare professional is permitted by the owner(s) of the
storage device to create and open records, then this
particular healthcare professional is the only individual
that is permitted to control the contents of these records.

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However, reading the data in this record is possible for at least the owner or owners of the storage device 1 and possibly for other persons or institutions as well. Moreover, the owner(s) of the storage device 1 is(are)

5   given the opportunity to add comments to every medical record.

          In principle, the entire database can only be accessed by the patient (the owner or owners in case one storage device is used by two or more patients) of the

10   storage device. The patient is asked to select the proper user (or create a new user) and to enter a password. Only with that password, his/her medical dossier can be opened. In this way the patient remains in full control of the access to his or her data / information.

15   The present invention is not limited to the above described preferred embodiments thereof; the rights sought are defined in the following claims, within the scope of which many modifications can be envisaged.